

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

BAUSCH & LOMB INCORPORATED, et  
al.,

Plaintiffs,

v.

GLAND PHARMA LIMITED,

Defendant.

Civil Action No. 22-4345 (MAS) (RLS)

MEMORANDUM OPINION  
AND ORDER

SINGH, United States Magistrate Judge.

**THIS MATTER** comes before the Court upon an informal discovery dispute raised pursuant to Local Civil Rule 37.1(a), by and between Plaintiffs Bausch & Lomb Incorporated, Bausch & Lomb Ireland Limited, and Nicox, S.A. (collectively, “Plaintiffs”) and Defendant Gland Pharma Limited (“Defendant”), regarding Defendant’s Invalidity Contentions For U.S. Patent Nos. 7,273,946, 7,629,345, 7,910,767, and 8,058,467 dated January 5, 2023 (the “Invalidity Contentions”). (Dkt. No. 33). Through the dispute, Plaintiffs seek the Court to compel Defendant to amend its Invalidity Contentions because, according to Plaintiffs, the Invalidity Contentions do not comply with Local Patent Rule 3.3(b). Defendant opposes the request, contending that its Invalidity Contentions meet the requirements of Local Patent Rule 3.3(b). (*See generally* Dkt. No. 33). The Court has fully reviewed the submissions of the parties and considered further argument of counsel during a March 8, 2023 telephone status conference. For the reasons set forth below, Plaintiff’s request to compel amendment of Defendant’s Invalidity Contentions is hereby **DENIED**.

## I. BACKGROUND AND PROCEDURAL HISTORY

As the facts and background are well-known to the parties and the Court, they are not set forth at length herein. Instead, only those facts and procedural history related to the instant dispute are discussed.

This case arises under 21 U.S.C. § 355 (commonly referred to as the “Hatch-Waxman Act”) based on Defendant’s submission of an Abbreviated New Drug Application (“ANDA”), seeking approval from the United States Food and Drug Administration (“FDA”) to market its generic latanoprostene bunod ophthalmic solution, 0.024% (“Defendant’s Generic Product”) prior to the expiration of United States Patent Nos. 7,273,946 (the “’946 Patent”), 7,629,345 (the “’345 Patent”), 7,910,767 (the “’767 Patent”), and 8,058,467 (the “’467 Patent”) (collectively, the “Patents-In-Suit”). (*See generally* Dkt. No. 1). Plaintiffs are the registered holder of a New Drug Application (“NDA”) for the drug Vyzulta®, which the FDA has approved to reduce intraocular pressure (“IOP”) in patients with open-angle glaucoma or ocular hypertension. (*See generally* Dkt. No. 1).

On or about January 5, 2023, Defendant served its Invalidity Contentions, contending that the asserted claims of the Patents-In-Suit are invalid based on obviousness pursuant to 35 U.S.C. § 103.<sup>1</sup> (*See* Dkt. No. 33-1). Through the Invalidity Contentions, Defendant identifies twenty (20) prior art references that it asserts either individually and/or in combinations thereof render the asserted claims of the Patents-in-Suit invalid as obvious. (*See* Dkt. No. 33-1).

## II. LEGAL STANDARD

Local Patent Rule 3.3(b) requires that a party serving invalidity contentions state

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<sup>1</sup> More specifically, Defendant asserts obviousness under 35 U.S.C. § 103(a), as existed prior to the Leahy-Smith America Invents Act (“AIA”). (*See* Dkt. No. 33-1 at p. 48).

“[w]hether each item of prior art . . . renders [a claim] obvious” and, where alleging obviousness, “an explanation of why the prior art renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness[.]” L. Pat. R. 3.3(b). The Rule requires that invalidity contentions “be detailed and specific in setting forth the prior art on which the party is relying[.]” *Merck Sharp & Dohme v. Sandoz*, No. 12-3289, 2014 WL 997532, at \*6 (D.N.J. Jan. 6, 2014). The required degree of specificity is that sufficient to provide reasonable notice to the patent holder. *See OKYN Holdings Inc. v. Hori (U.S.A.) Inc.*, No. 21-4796, 2022 WL 2189527, at \*2 (C.D. Cal. April 5, 2022) (quoting *Geovector Corp. v. Samsung Electrs. Co.*, No. 16-2463, 2017 WL 76950, at \*3) (N.D. Cal. Jan. 9, 2017)).

Local Patent Rule 3.3 furthers the Local Patent Rules’ goal of promoting early discovery and notice of contentions, particularly in cases arising under the Hatch-Waxman Act. *See Warner Chilcott Co. v. Mylan*, No. 13-6560, 2015 WL 3630970, at \*6 (D.N.J. June 10, 2015) (recognizing the Local Patent Rules serve to promote timely discovery and “adequate notice” (quoting *Computer Acceleration Corp. v. Microsoft Corp.*, 503 F. Supp. 2d 819, 822 (E.D. Tex. 2007)); *Sanofi-Aventis v. Barr Labs.*, 598 F. Supp. 2d 632, 637 (D.N.J. 2009) (recognizing that the Local Patent Rules require early disclosure of infringement and invalidity contentions in Hatch-Waxman cases). As in other jurisdictions with corollary Local Patent Rules, this District similarly designed the Local Patent Rules to task litigants with the obligations of crystallizing and committing to their legal theories early in the case. *See Celgene Corp. v. Natco Pharma Ltd.*, No. 10-5197, 2015 WL 4138982, at \*4 (D.N.J. July 9, 2015) (quoting *Atmel Corp. v. Info. Storage Devices, Inc.*, No. 95-1987, 1998 WL 775115, at \*2 (N.D. Cal. Nov. 5, 1998)).<sup>2</sup>

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<sup>2</sup> This Court often looks to decisions from the Northern District of California and the Eastern District of Texas, which have adopted patent rules similar to the District of New Jersey’s Local Patent Rules. *See, e.g., Cochlear Ltd. v. Oticon Med. AB*, No. 18-6684, 2019 WL 3429610, at \*7

### III. DISCUSSION

Plaintiffs contend that Defendant's Invalidity Contentions fail to meet Local Patent Rule 3.3 by insufficiently specifying the combinations of prior art that Defendant maintains render the asserted claims obvious. (See Dkt. No. 33 at p. 3). Plaintiffs point to a Special Discovery Master Report and Recommendation in *Celgene Corporation v. Hetero Labs Limited*, 2021 U.S. Dist. LEXIS 159262 (D.N.J. Mar. 29, 2021), for the proposition that Defendant's use of "vague catch-all language" in its contentions does not help to crystallize the issues in the case at an early stage. (Dkt. No. 33 at p. 3 (discussing and citing *Hetero Labs Ltd.*, 2021 U.S. Dist. LEXIS 159262 (Report & Recommendation))). Plaintiffs accordingly seek the Court to compel Defendant to amend its Invalidity Contentions to provide more specificity as to the combinations of prior art upon which intends to assert.

Defendant, however, counters that its Invalidity Contentions comply with Local Patent Rule 3.3. (See Dkt. No. 33 at p. 4). It posits that it has identified twenty (20) prior art references, with explanations of the relevant teachings and combinations thereof that render the asserted claims as obvious. (See Dkt. No. 33 at p. 4). Defendant further explains that the identified prior art references fall "broadly into two categories," within which many of the references overlap and disclose similar subject matter. (Dkt. No. 33 at p. 4). According to Defendant, its Invalidity Contentions adequately discloses the combinations of prior art from each category to support its obviousness theories, and the number of potential combinations is therefore not "excessive." (Dkt. No. 33 at pp. 4-5).

As a threshold matter, the Court recognizes that this District has often considered the sufficiency of invalidity contentions in the context of a motion for leave to amend contentions

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(D.N.J. July 29, 2019); *Celgene*, 2015 WL 4138982, at \*4; *Voxpath RS v. LG Elecs.*, No. 12-952, 2012 WL 5818143, at \*3 (D.N.J. Nov. 14, 2012).

under Local Patent Rule 3.7 or at the expert discovery phase. *See, e.g., Celgene*, 2015 WL 4138982, at \*1; *Warner Chilcott*, 2015 WL 3630970, at \*1; *Merck Sharp*, 2014 WL 997532, at \*1. Nevertheless, the Court finds that Plaintiff brings this application at the appropriate juncture to seek relief for compliance with Local Patent Rule 3.3. *See Personalized Media Comm's LLC v. Apple Inc.*, No. 15-1366, 2021 WL 310789, at \*2 (E.D. Tex. Jan. 29, 2021) (finding that, where the movant challenged the sufficiency of invalidity contentions under corollary Local Patent Rule 3-3, “[t]he relief requested would have been more appropriate had it been requested concurrent with Apple’s service of invalidity contentions”).

While the case law often discusses the adequacy of invalidity contentions in a different procedural posture than that presented here, those cases nonetheless provide the Court with guidance in construing compliance with Local Patent Rule 3.3. Notably, the Special Discovery Master in the case relied upon by Plaintiffs, *Celgene Corp. v. Hetero Labs Ltd.*, considered whether the defendant’s invalidity contentions sufficiently disclosed that it would rely on combinations of prior art in the context of a motion to strike an expert report. *Hetero Labs*, 2021 U.S. Dist. LEXIS 159262, at \*62. In that case, the defendant’s invalidity contentions listed over 100 prior art references, stated that it “‘reserve[d] the right to rely on any of the above listed references as anticipating or rendering obvious one or more of the Asserted Claims,’” and identified eighteen (18) “exemplary” non-exhaustive combinations. *Id.* at \*63-64 (quoting the defendant’s invalidity contentions)). At the expert stage, the defendant proffered an expert report that opined certain combinations of the previously disclosed prior art references rendered the asserted claims obvious, but those combinations were not disclosed in the invalidity contentions’ “exemplary” combinations. *Id.* at \*64. In recommending that the Court strike the newly disclosed combinations, the Special Discovery Master found the defendant was “short-circuiting” Local

Patent Rule 3.3 by “stating that any possible combination of that multitude of material has been sufficiently disclosed[,]” thereby resulting in “a potential set of permutations and combinations numbering in the hundreds, or more, without saying anything about them, or even specifically identifying them,” as required by the Local Patent Rule. *Id.* at \*68.

The Court finds the situation here different than that presented to the Special Discovery Master in *Celgene*. Here, Defendant identifies the twenty (20) prior art references on which it relies and explains how the prior art purportedly renders the asserted claims obvious by discussing the prior art and prior art combinations that, for example, would have led a person of ordinary skill in the art to use the “lead compound,” latanoprost, with a nitric oxide (“NO”) donating group. (See Dkt. No. 33-1 at pp. 33-72). In contrast to the defendant in *Celgene*, Defendant, here, identifies specific combination groups in support of its claims of obviousness. (See, e.g., Dkt. No. 33-1 at pp. 58-59). The Court, therefore, finds that Defendant satisfies its obligations under Local Patent Rule 3.3. See, e.g., *Avago Tech. Gen. IP PTE Ltd. v. Elan Microelectronics Corp.*, No. 04-5385, 2007 WL 951818, at \*4 (N.D. Cal. Mar. 28, 2007) (finding the defendant “reasonably specific[d] the combination of prior art references” that allegedly rendered the patents-in-suit obvious where the defendant organized the prior art references into two groups and contended that the “theory of obviousness is the same for each and every possible combinations of the two groups”).

While Defendant does include broad language such as “or in further combination with other prior art references and the general knowledge in the art,” (Dkt. No. 33-1 at pp. 58-59), the Court reads such language in the context of the entirety of the Invalidity Contentions, which do disclose more specific combination groupings. See *Personalized Media*, 2021 WL 310789, at \*3 (finding the invalidity contentions sufficiently notified the patent holder of “the sorts of combinations on which it will later rely” when viewing the contentions as a whole, although the “list may indeed

result in a vast number of possible combinations”); *Avago Tech.*, 2007 WL 951818, at \*4 (finding the invalidity contentions sufficiently complied with similar local patent rule although the combinations would result “in literally billions of different possible combinations” (footnote omitted)). In addition, the Court also notes that Plaintiff is not unduly prejudiced by declining to grant the relief requested. Defendant will not be able shift its theories without timely seeking leave to amend under Local Patent Rule 3.7. Moreover, this case is still in its early stages. As the case proceeds, the parties may meet and confer—or the Court may require such meet and confer—as to any potential limitations on the number of asserted claims and/or prior art references.

Accordingly, for the reasons set forth herein, the Court denies Plaintiff’s request to compel Defendant to revise its Invalidity Contentions.

#### **IV. CONCLUSION**

Having considered the submissions of the parties, and for the reasons set forth above,

**IT IS, THEREFORE**, on this 14th day of March 2023,

**ORDERED** that Plaintiff’s informal application to compel (Dkt. No. 33) is hereby **DENIED**; and it is further

**ORDERED** that, by no later than March 20, 2023, the parties shall file a joint proposed amended scheduling order.

**SO ORDERED.**

  
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**RUKHSANAH L. SINGH**  
**UNITED STATES MAGISTRATE JUDGE**